

IMproving the PReoperative StatuS of patients undergoing major surgery

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The use of the 'Beter Voorbereid' eHealth application modifies risk behaviour and improves the patients functional capacity which leads to a better functional recovery after surgery.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28174

Bron

NTR

Verkorte titel

IMPRESS

Aandoening

Major surgery with an indication for postoperative hospital stay

Ondersteuning

Primaire sponsor: VUmc

Overige ondersteuning: Foundation Innovative Alliance – Regional Attention and Action for Knowledge circulation (SIA-RAAK).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Course of functional recovery, PROMIS CAT Physical Functioning

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The eHealth application 'Beter Voorbereid' is an eHealth application that uses a set of questions to map a patient's lifestyle risk factors for delayed postoperative recovery in patients undergoing major surgery. Based on the lifestyle risk profile of the patient, a tailored preoperative lifestyle advice is provided. Furthermore, the patient can use the eHealth application to make an appointment with a local physiotherapist to improve the physical fitness of the patient under supervision. The eHealth application can be displayed on a smartphone and tablet. The application is offered to the patient during his/her visit to the preoperative outpatient clinic. It is currently unknown whether the use of an app to advise patients in improving their pre-operative lifestyle is more beneficial than usual care in enhancing functional recovery after surgery.

Objective: To investigate whether use of the 'Beter Voorbereid' application is associated with improved functional recovery after surgery when compared to control patients

Study design: A multicenter randomized controlled trial (RCT) will be conducted.

Intervention: Use of an eHealth application for prehabilitation of surgical patients in the preoperative period. The intervention group is compared to control subjects receiving usual care.

Main study outcomes: Primary outcome is the course of functional recovery after surgery. Secondary outcomes are functional recovery, in-hospital physical symptoms, physical functioning and psychological functioning, social participation, patient satisfaction, global health, lifestyle risk factors and peri-operative factors.

Doel van het onderzoek

The use of the 'Beter Voorbereid' eHealth application modifies risk behaviour and improves the patients functional capacity which leads to a better functional recovery after surgery.

Onderzoeksopzet

Five time points, at baseline and 1 week, 3 weeks, 6 weeks and 12 weeks after hospital discharge.

Onderzoeksproduct en/of interventie

The eHealth application is a mobile application, which participants have to download to their device. The app can be used on smartphones and tablets.

Participants receive support in optimizing their health and lifestyle in the peri-operative period. Participants with an indication to enhance preoperative physical fitness have the

possibility to enhance their fitness under supervision of a specialized local physiotherapist, who can be found via the app. The total package of advices may include smoking cessation, lowering of alcohol intake, nutritional advices and exercise advices (physical activity increase and/or muscle strengthening). The advices consists of specific tasks the patient can perform based on the personal profile of the patient. Advices are provided in the pre-operative period, as well as in the direct post-operative period. The participant receives feedback on the tasks performed using the application.

Contactpersonen

Publiek

VUmc
MARIKE van der leeden

+31 (0)20 4444256

Wetenschappelijk

VUmc
MARIKE van der leeden

+31 (0)20 4444256

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients age 18 years or older undergoing major surgery with an indication for postoperative hospital stay will be recruited within the participating hospitals. In order to be eligible to participate, the patient must meet the following criteria:

1. Age $\geq$ 18 years old
2. Indication for postoperative hospital stay (minimum of two nights)
3. One or more lifestyle risk factors (smoking , alcohol intake, exercise/physical activity, nutrition/weight)
4. Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Emergency surgery
2. Unable to work with the eHealth application
3. Dutch language inproficiency
4. No access to a tablet or smartphone
5. Less than 7 days between inclusion and surgery
6. Planned for brain surgery (due to possible cognitive impairments post-surgery and related problems with filling in questionnaires)
7. Already participating in intensive pre-operative care pathway (including exercise program/physiotherapy)
8. Already participating in a conflicting study (to be determined per participating center)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2020
Aantal proefpersonen:	480
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 14-05-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53078

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8623
CCMO	NL61503.029.18
OMON	NL-OMON53078

Resultaten